PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**CHEN, HORN**
Application No.:	**09/716757**
Filed:	**November 20, 2000**
For:	**Hybrid Sleeve Material and Structure**
Examiner:	**Urmi Chattopadhyay**
Group Art Unit:	**3738**
Firm Docket No.:	**S63.2B-9494-US01**

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FACSIMILE TRANSMITTAL LETTER

Following please find a 16 page Brief on Appeal; and 1 page Facsimile Transmittal Letter. This brief is being filed in response to the Examiner's request for an amended brief.

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Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

Date: December 10, 2003

By: _____
Richard A. Arrett
Registration No.: 33153

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-9494-US01

BRIEF ON APPEAL

This is a Brief on Appeal for the above-identified application in which claims 1-5 and 9-12 were finally rejected in an Office Action mailed February 4, 2003. A Notice of Appeal was filed June 3, 2003. The fees required under §1.17(f) and any required petition for extension of time for filing this brief therefore are dealt with in the accompanying Transmittal of Appeal Brief. This brief is transmitted in triplicate in accordance with 37 C.F.R. §1.192(a).

(1) Real Party in Interest

The application is assigned to SCIMED Life Systems, Inc., a Minnesota corporation.

(2) Related Appeals and Interferences

No related appeals or interferences are pending.

(3) Status of Claims

Claims 1-12 are pending in the application. Claim 6 is allowed. Claims 7-8 have withdrawn from consideration. Claims 1-5 and 9-12 have been rejected and are the subject of this appeal.

(4) Status of Amendments

An Amendment After Final was submitted on April 11, 2003. In an Advisory Action mailed May 2, 2003, the Examiner stated that the amendment would be entered upon filing of a Notice of Appeal, and that the amendment canceling claim 13 would overcome the rejection of claim 13. A Notice of Appeal was filed June 3, 2003. Accordingly it is understood that the April 11, 2003 Amendment After Final has now been entered, that claim 13 has been cancelled, and the specification has been amended to overcome the objection to the specification of paragraph 2 of the action, and that consequently no unentered Amendments remain outstanding.

Applicant is submitting a proposed amendment with this appeal to fix a grammar problem in claim 3, which currently reads "is least 55D", to change the text to read "is at least 55D".

(5) Summary of the Invention

The instant invention is directed to a medical device delivery system comprising a catheter assembly having a medical device receiving region and at least one retaining sleeve for retaining the medical device on the receiving region prior to delivery. An expandable medical device, such as a stent, is disposed about the medical device

receiving region of the catheter assembly. At least one retaining sleeve is disposed about an end of the expandable medical device and at least a portion of the catheter assembly. (See Specification, Summary of Invention, 1st paragraph).

The at least one retaining sleeve further comprises an inside surface and an outside surface. The outside surface being comprised of a first material and at least the portion of the inside surface which is constructed to overlay a stent being comprised of a second material. The first and second materials having different harnesses, the second material being harder than the first. As is known, for most polymer materials, the hardness represents the capacity of elongation when the polymer is exposed to an outside acting force, this is especially true for elastomeric materials (e.g. the lower a material's hardness the higher the material's elasticity). (See Specification, Summary of Invention, 2nd paragraph).

Unlike the 09/668,496 application, from which the present application depends, and which provides for a sleeve having reduced longitudinal elongation, the present invention improves sleeve retractability by providing at least the portion of the inside surface of the sleeve which may overlay a stent with a material which has a greater hardness than the majority of the sleeve material. Such a relatively hard material preferably provides the sleeve with a surface having lower frictional engagement to the stent. (See Specification, Summary of Invention, 3rd paragraph).

In an embodiment of the invention the first material and second material are co-extruded polymers. (See Specification, Summary of Invention, 4th paragraph).

In an embodiment of the invention the second material is a coating on the first material. (See Specification, Summary of Invention, 5th paragraph).

In an embodiment of the invention the inside surface is comprised entirely of the second material. (See Specification, Summary of Invention, 6th paragraph). (See Specification, Summary of Invention, 5th paragraph).

In an embodiment of the invention only the portion of the inside surface which is constructed and arranged to overlay a stent is comprised of the harder material. (See Specification, Summary of Invention, 7th paragraph).

The invention of claim 1 relates to a stent delivery catheter with at least one stent retaining sleeve overlying an end of a stent, the stent retaining sleeve having an outside surface and an inside surface, the outside surface being composed of a first material having a first predetermined hardness and the inside surface being composed of a second material having a second predetermined hardness, the second predetermined hardness having a higher durometer value than the first predetermined hardness. (See Specification page 6, lines 16-24 and page 6, line 31 – page 7, line 10).

The invention of claim 2 depends from claim 1 and further relates to the second material being smoother than the first material. (Claim 2 as filed).

The invention of claim 3 depends from claim 1 and further relates to the first predetermined hardness being less than approximately 55D, and the second predetermined hardness being at least 55D. (Specification page 7, lines 5-10).

The invention of claim 4 depends from claim 1 and further relates to the first predetermined hardness being approximately 35D, and the second predetermined hardness being approximately 55D. (Specification page 8, lines 7-10).

The invention of claim 5 depends from claim 1 and further relates to the inside surface being comprised of the second material. (Specification page 7, lines 3-4).

The invention of claim 9 depends from claim 1 and further relates to the first material being constructed from at least one member of the group consisting of: styrenic block copolymers, polyurethanes, silicone rubber, natural rubber, copolyesters, polyamides, EPDM rubber/polyolefin, nitril rubber/PVC, fluoroelastomers, butyl rubber, epichlorohydrin, polyester elastomers, polyamide elastomers and any combination thereof. (Specification page 7, lines 11-22).

The invention of claim 10 depends from claim 1 and further relates to the second material being constructed from at least one member of the group consisting of: polyolefins, polystyrene, polyvinyl chloride, acrylonitrile-butadiene-styrene polymers, polyacrylonitrile, polyacrylate, vinyl acetate polymer, cellulose plastics, polyurethanes, polyethylene terephthalate, polyacetal, polyethers, polycarbonates, polyamides, polyphenylene sulfide, polyarylethersulfones, polyaryletherketones, polytetrafluoroethylene, and any combination thereof. (Specification page 7, lines 23 – page 8, lines 1-5).

The invention of claim 11 relates to a stent retaining sleeve for retaining stent ends on a balloon catheter. The stent retaining sleeve having an outside surface and an inside surface, the outside surface being composed of a first material having a first predetermined hardness and the inside surface being composed of a second material having a second predetermined hardness, the second predetermined hardness having a higher durometer value than the first predetermined hardness. (See Specification page 6, lines 16-24 and page 6, line 31 – page 7, line 10). The stent retaining sleeve of claim 11 also having first and second ends, the inside surface of the first end constructed and

arranged to overlay an end of a stent, the second end constructed and arranged to be in contact with at least a portion of a catheter. (See Specification page 6, lines 16-26).

The invention of claim 12 relates to a stent delivery system with at least one stent retaining sleeve overlying an end of a stent, the stent retaining sleeve having an outside surface and an inside surface, the inside surface being harder than the outside surface (See Specification page 6, lines 16-24 and page 6, line 31 – page 7, line 10).

(6) Issues

I. Did the examiner err in rejecting claims 1-5 and 9-12 as anticipated under 35 USC §102(e) by Willard US 5980530.

(7) Grouping of Claims

For purposes of issue I:

Claims 1, 5, 9, 10 and 11 stand or fall together.

Claim 2 stands or falls alone.

Claim 3 stands or falls alone.

Claim 4 stands or falls alone.

Claim 12 stands or falls alone.

(8) Argument

I. THE EXAMINER ERRED IN REJECTING CLAIMS 1-5, and 9-12 AS ANTICIPATED BY WILLARD US 5980530

A. Claims 1, 5, 9, 10 and 11

Claim 1 requires, in part, at least one stent retaining sleeve having an inside surface and an outside surface . . . the outside surface being composed of a first material, and the inside surface being composed of a second material. Willard discloses sleeves 22 and 24, but the sleeves are composed of only a single material, such as polyurethane, silicone, latex or polyether amide (Col. 3, lines 40-54).

The Examiner is treating reinforcing ring 34 from Willard as **part of** the sleeve of Willard. Willard discloses that the entire sleeve be formed from polyurethane tubing (Col. 3 lines 40-54), and therefore both the inside and outside surface of the sleeve is taught as being made from the same material, polyurethane. Willard does not teach that the reinforcing ring 34 is part of the sleeve, but only that the reinforcing ring **is attached** to the sleeve under the overlapping portion of the sleeve in contact with the stent. Willard does not teach that rings 34 are considered part of the sleeve or the inside surface of the sleeve. The function of the rings 34 is to compress the stent and hold it down. (Willard Col. 3, lines 65). For this first reason, Willard does not anticipate claims 1, 5, 9, 10 and 11.

Claims 1, 5, 9, 10 and 11 each require that the inner surface of the sleeve be composed of the second material, i.e. the entire inside surface. Even if ring 34 is considered to be part of the sleeve 22 (which applicant does not concede) the entire inside surface of the sleeve is not composed of the second material, as required by claims 1, 5, 9, 10 and 11. For this second reason, Willard does not anticipate claims 1, 5, 9, 10 and 11.

Finally, claims 1, 5, 9, 10 and 11 require that the inside surface of the sleeve (the second material) be harder than the outside surface (the first material). As discussed

above, Willard discloses a polyurethane tube in which the inside and outside surface have the same hardness. For this third reason, Willard does not anticipate claims 1, 5, 9, 10 and 11.

Even if the ring was considered the entire inner surface of the sleeve (which it is not) Willard US 5980530 teaches the equivalence of using either metal or plastic for the reinforcing rings 34. (Col. 3, lines 60-61). The specification of Willard specifically teaches that "[a]ny body compatible metal and plastic having the requisite strength characteristics, and/or other physical characteristics may be used in the various embodiments of this invention." (Col. 4 lines 55-58). There is nothing taught, suggested or disclosed in Willard which motivates a ring material which is necessarily harder than the sleeve material (polyurethane, silicone, latex or polyether amide)(Col. 3, lines 48-50).

Of the materials taught as equivalent for the ring material (metal, polyimide or polyethylene – Col. 3, lines 60-62), polyimide and polyethylene are commercially available in shore D hardness ranges which overlap with polyurethane[1] (the first material), such that the sleeve material of Willard (polyurethane) **could** be harder than the polyethylene (a ring material) of Willard.

In Trintec Industries Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597 (Fed. Cir. 2002), the Federal Circuit stated that "[i]nherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in

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[1] In its amendment after final – which was entered and considered, applicant cited the following web sites as examples of commercially available materials which overlapped in hardness:

http://www.polyurethane-1.com/hardness.htm - Polyurethane elastomers can be formulated to cover a wide hardness range, from 30 Shore A to 85 Shore D.

http://www.ptsuk.com/products/frmProd_Engineering.html - Riteflex polyester copolymer elastomers. Unreinforced Shore D hardness range 40 to 77.

the prior art." Therefore, Willard does not **inherently** anticipate claims 1, 5, 9, 10 and 11, because:

1) the sleeve of Willard is formed from a single material and the ring of Willard is not part of the sleeve of Willard;

2) the ring of Willard does not form the entire inner surface of the sleeve of Willard; and

3) Willard fails to teach, suggest or motivate having a first material which is "necessarily" softer than the second material.

B. Claim 2

Because claim 2 is dependent from claim 1, all of the arguments made above in connection with claim 1 apply to claim 2. In addition, Claim 2 requires that the second material is smoother than the first material. Willard fails to disclose or teach that the entire inner surface of the sleeve is smoother than the outside surface. In fact Willard discloses that the entire sleeve, both the inside and outside surface is made from the same material (Col. 3 lines 40-54) and says nothing about the inner surface of the sleeve being smoother than the outer surface.

Even if the ring is considered to form part of the inner surface of the sleeve (which applicant does not concede) the remainder of the inner surface of the sleeve is comprised of the same material as the outside surface of the sleeve – and is therefore not smoother. Also, given the three equivalent materials taught as ring material, there is no inherent disclosure **necessarily** resulting in a ring material which is smoother than the material comprising the sleeve.

C. Claim 3

Because claim 3 is dependent from claim 1, all of the arguments made above in connection with claim 1 apply to claim 3. In addition, claim 3 requires that the first predetermined hardness (the hardness of the first material) be less than approximately 55D and the second predetermined hardness (the hardness of the second material) be at least 55D.

There is no disclosure at all in Willard related to a sleeve formed of two materials, the first or outside material having a hardness of less than approximately 55D and the second or inside surface having a hardness of at least 55D. Willard does not teach a sleeve made of two separate materials and it also does not teach a sleeve where the ring is necessarily harder than the sleeve material. Given the commercial availability of the two materials with (sleeve and ring) overlapping hardness, Willard US 5980530 does not inherently teach a sleeve formed of two materials, the first or outside material having a hardness of less than approximately 55D and the second or inside surface having a hardness of at least 55D.

D. Claim 4

Because claim 4 is dependent from claim 1, all of the arguments made above in connection with claim 1 apply to claim 4. In addition, claim 4 requires that the first predetermined hardness (the hardness of the first material) be less than approximately 35D and the second predetermined hardness (the hardness of the second material) is approximately 55D.

There is no disclosure at all in Willard related to a sleeve formed of two materials, the first or outside material having a hardness of less than approximately 35D and the second or inside surface having a hardness of approximately 55D. Willard does not teach a sleeve made of two separate materials and it also does not teach a sleeve where the ring is necessarily harder than the sleeve material. Given the commercial availability of the two materials with (sleeve and ring) overlapping hardness, Willard US 5980530 does not inherently teach a sleeve formed of two materials, the first or outside material having a hardness of less than approximately 35D and the second or inside surface having a hardness of approximately 55D.

E. Claim 12

Claim 12 requires, in part, at least one stent retaining sleeve . . . having an inside surface and an outside surface, the inside surface characterized as being harder than the outside surface.

Like claim 1, claim 12 requires that the entire inside surface be harder than the outside surface. As discussed above, Willard does not disclose a two material sleeve, but a tube having the same material on the inside surface as on the outside surface. Therefore, Willard does not meet the limitations of claim 12.

The Examiner is treating reinforcing ring 34 from Willard as **part of** the sleeve of Willard. Willard discloses that the entire sleeve be formed from polyurethane tubing (Col. 3 lines 40-54), and therefore both the inside and outside surface of the sleeve is taught as being made from the same material, polyurethane. Willard does not teach that the reinforcing ring 34 is part of the sleeve, but only that the reinforcing ring **is attached** to the sleeve under the overlapping portion of the sleeve in contact with the stent.

Willard does not teach that rings 34 are considered part of the sleeve or the inside surface of the sleeve. The function of the rings 34 is to compress the stent and hold it down. (Willard Col. 3, lines 65). For this reason, Willard does not anticipate claim12.

Claim 12 requires that the inner surface of the sleeve be harder than the outside surface, i.e. the entire inside surface. Even if ring 34 is considered to be part of the sleeve 22 (which applicant does not concede) the entire inside surface of the sleeve is not harder than the outside surface, as required by claim12. For this reason, Willard does not anticipate claim 12.

Even if the ring was considered the entire inner surface of the sleeve (which it is not) Willard US 5980530 teaches the equivalence of using either metal or plastic for the reinforcing rings 34. (Col. 3, lines 60-61). The specification of Willard specifically teaches that "[a]ny body compatible metal and plastic having the requisite strength characteristics, and/or other physical characteristics may be used in the various embodiments of this invention." (Col. 4 lines 55-58). There is nothing taught, suggested or disclosed in Willard which motivates a ring material which is **necessarily** harder than the sleeve material (polyurethane, silicone, latex or polyether amide)(Col. 3, lines 48-50).

Of the materials taught as equivalent for the ring material (metal, polyimide or polyethylene – Col. 3, lines 60-62), polyimide and polyethylene are commercially available in shore D hardness ranges which overlap with polyurethane (see footnote 1 above)(the first material), such that the sleeve material of Willard (polyurethane) **could** be harder than the polyethylene (a ring material) of Willard.

In Trintec Industries Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597 (Fed. Cir. 2002), the Federal Circuit stated that "[i]nherent anticipation requires that the missing

descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." Therefore, Willard does not **inherently** anticipate claim 12, because:

1) the sleeve of Willard is formed from a single material and the ring of Willard is not part of the sleeve of Willard;

2) the ring of Willard does not form the entire inner surface of the sleeve of Willard; and

3) Willard fails to teach, suggest or motivate a ring material which is "necessarily" harder than the sleeve material.

CONCLUSION

Based on the foregoing, applicant believes that the Examiner has misread and misapplied Willard. Therefore, the Board is respectfully requested to reverse the §102(e) rejection of claims 1-5 and 9-12.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: ~~September 5, 2003~~ 12/10/03

By: _____
Richard A. Arrett
Registration No.: 33153

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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(9) **Appendix - Claims on Appeal**

Claims rejected: 1-5 and 9-12

1. A stent delivery system comprising:

a catheter including a stent mounting region;

a stent disposed about the stent mounting region of the catheter, the stent having a distal end and a proximal end, the stent further having an unexpanded state and an expanded state, and

at least one stent retaining sleeve, the at least one stent retaining sleeve having an inside surface and an outside surface and a first end and a second end,

the first end overlying an end of the stent when the stent is in the unexpanded state, the second end engaged to at least a portion of the catheter adjacent to the stent mounting region;

the outside surface being composed of a first material, and the inside surface being composed of a second material;

the first material having a first predetermined hardness, the second material having a second predetermined hardness, the second predetermined hardness having a higher durometer value than the first predetermined hardness.

2. The stent delivery catheter of claim 1 wherein the second material is smoother than the first material.

3. The stent delivery catheter of claim 1 wherein the first predetermined hardness is less than approximately 55D, and the second predetermined hardness is at[2] least 55D.

4. The stent delivery catheter of claim 1 wherein the first predetermined hardness is approximately 35D, and the second predetermined hardness is approximately 55D.

5. The stent delivery catheter of claim 1 wherein the inside surface is comprised of the second material.

9. The stent delivery system of claim 1 wherein the first material is constructed from at least one member of the group consisting of: styrenic block copolymers, polyurethanes, silicone rubber, natural rubber, copolyesters, polyamides, EPDM rubber/polyolefin, nitril rubber/PVC, fluoroelastomers, butyl rubber, epichlorohydrin, polyester elastomers, polyamide elastomers and any combination thereof.

10. The stent delivery system of claim 1 wherein the second material is constructed from at least one member of the group consisting of: polyolefins, polystyrene, polyvinyl chloride, acrylonitrile-butadiene-styrene polymers, polyacrylonitrile, polyacrylate, vinyl acetate polymer, cellulose plastics, polyurethanes, polyethylene terephthalate, polyacetal, polyethers, polycarbonates, polyamides, polyphenylene sulfide, polyarylethersulfones, polyaryletherketones, polytetrafluoroethylene, and any combination thereof.

11. A stent retaining sleeve for retaining stent ends on a balloon catheter comprising:

a first material and a second material, wherein the first material has a first predetermined hardness and the second material has a second predetermined hardness, the second predetermined hardness being greater than the first predetermined hardness;

the stent retaining sleeve having an inside surface and an outside surface, and a first end and a second end, the inside surface of the first end constructed and arranged to overlay an end of a stent, the second end constructed and arranged to be in contact with at least a portion of a catheter;

the inside surface of the first end being composed of the second material.

12. A stent delivery system comprising:

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[2] Proposed amendment being submitted with appeal brief.

a catheter including a stent mounting region;

a stent disposed about the stent mounting region of the catheter, the stent having a distal end and a proximal end, the stent further having an unexpanded state and an expanded state, and

at least one stent retaining sleeve, the at least one stent retaining sleeve having a first end and a second end, the first end overlying an end of the stent when the stent is in the unexpanded state, the second end engaged to at least a portion of the catheter adjacent to the stent mounting region;

the at least one sleeve having an inside surface and an outside surface, the inside surface characterized as being harder than the outside surface.